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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,346	03/01/1999	SHAI YARKONI	1268-073	1591

1444 7590 09/13/2004
BROWDY AND NEIMARK, P.L.L.C.
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SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/147,346

Applicant(s)

YARKONI ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9,10,21-28,30-33,35 and 36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9,10,21-28,30-33,35 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Claims 1, 3-7, 9-10, 21-28, 30-33, 35, have been amended.
Claim 36 has been added.
Claims 2, 8, 11-20, 29, 34 have been canceled.
Claims 1, 3-7, 9-10, 21-28, 30-33, 35-36 are pending and under examination.
2. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
3. The following Office Action contains NEW GROUNDS of rejection.

Claim Objections

4. Claim 36 is objected to as depending from a canceled claim, claim 29.

Rejections Withdrawn

5. The rejection of claims 30-34 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.
6. The rejection of claims 33 and 34 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

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had possession of the claimed invention is withdrawn in view of arguments and amendments.

Response to Arguments

7. The rejection of claims 1, 3-7, 21, 23-28, 30-33, 35 and newly added claim 36 under 35 U.S.C. 103(a) as being unpatentable over Nett et al (U.S. Patent 5,378,688, issued 1/95), and further in view of Chaudhary et al {a} (Nature 339:394-397, 1989, PTO-892 paper #11) and Chaudhary et al {b} (Proc. Natl. Acad. Sci. USA 84:4538-4542, 1987, PTO-892, paper #11) and as evidenced by the specification is maintained.

The response filed 4/30/04 has been carefully considered but is deemed not to be persuasive. The response states that the chimeric protein of the present invention has a different structure that is different from Nett and prior to the present invention it was not known that the adenocarcinoma cells had GnRH binding sites (see pages 10-11) and the fusion protein in the present invention is produced bacterially and thus has a Met residue as shown in Figure 1 preceding the peptide and this is different from Nett and a new declaration by Dr. Lorberbourn-Galski is attached and the Met-GnRH of the present invention is different from the GnRH used by Nett and the fusion protein of the present invention selectively targets cells having distinctively different GnRH binding sites on adenocarcinomas (see page 11-12) and the response states that there are unexpected results because of the unexpected difference in activity (see page 15 of response).

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In response to these arguments, the declaration of Dr. Lorberboum-Galski has been carefully considered but is deemed not to be persuasive. The claims rejected are directed to produces comprising a Met-GNRH and a killing moiety. Although the response states there is a difference between the bacterially produced fusion protein that has a Met at the N-terminus, the rejection stated that it is routine in the art to add an ATG codon to the 5' of the nucleic acid to express the fusion protein in E. coli as taught by Chaudhary. Thus, there would be no difference between the claimed fusion proteins and that of the prior art. The response further states that the conjugates recognize and target different receptors and the GnRH-based chimeric protein target and kill adenocarcinoma cells and this is demonstrated in the declaration of Dr. Lorberboum-Galski. In response to this argument, the declaration has been carefully considered but is deemed not to be persuasive because the molecules that would result from the combination of Nett et al and Chaudary et al would be the same as those claimed and as such would obviously target the adenocarcinoma cells binding sites. The product claimed and the products produced by the combination of the prior art would result in targeting the binding sites on adenocarcinoma cells because the products are the same, Met-GnRH-PE conjugates.

8. The rejection of claims 1, 3-7, 9-10, 21-28, 30-33 and newly added claim 36 under 35 U.S.C. 103(a) as being unpatentable over Nett et al (U.S. Patent 5,378,688, issued 1/95), and further in view of Chaudhary et al {a} (Nature 339:394-397, 1989, PTO-892 paper #11) and Chaudhary et al {b} (Proc. Natl. Acad. Sci. USA 84:4538-

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4542, 1987, PTO-892, paper #11) and Imai et al (Cancer 74:2555-61, 1994) and as evidenced by the specification is maintained.

The response filed 4/30/04 has been carefully considered but is deemed not to be persuasive. The response states that Imai adds nothing to the teachings of Nett or Chaudhary and there is nothing about adenocarcinoma cells being targeted (see page 17-18 of response). In response to this argument, again for those claims that are to the product, the arts product is the same as the claimed products, see above response. In response to Imai does not teach adenocarcinoma cells, claims 23-28 do not require this. For those claims that require adenocarcinoma cells, Imai teach cystadenocarcinoma that have the GnRHR (see Table 1).

Conclusion

9. No claim is allowed.
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

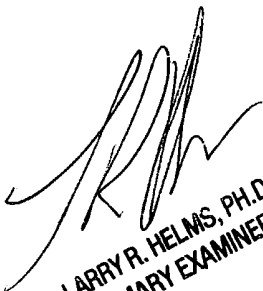
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached at (571) 272-0787.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Respectfully,

Larry R. Helms Ph.D.

571-272-0832



LARRY R. HELMS, PH.D
PRIMARY EXAMINER